

April 26, 2019

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460

Re: National Emissions Standards for Hazardous Air Pollutants: Hydrochloric Acid
Production Residual Risk and Technology Review, Docket ID No. EPA-HQ-
OAR-2018-0417

Dear Administrator Wheeler,

The Northwestern Law Environmental Advocacy Center (“EAC”), on behalf of Stop EtO in Lake County, respectfully submits these comments on the proposed amendments to the National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for the Hydrochloric Acid (“HCl”) Production source category, which also seeks comments on the risk value for ethylene oxide (“EtO”).

The EAC is part of the Bluhm Legal Clinic at Northwestern Pritzker School of Law in Chicago, IL. The EAC focuses its efforts on environmental protection and working to protect the health and well-being of communities, including environmental justice communities. Our client, Stop EtO in Lake County, is a community group comprised of Lake County, Illinois residents from Gurnee, Waukegan, and nearby smaller communities. Waukegan, and some of the nearby communities are environmental justice communities with limited resources facing health and environmental risks from exposures to hazardous pollutants, including EtO.

There are two facilities that use and emit thousands of pounds of highly toxic and carcinogenic EtO within three miles of each other in the Lake County area. In Gurnee, Vantage Specialty Chemicals uses ethylene oxide to produce personal care products, consumer products, and food. In Waukegan, Medline Industries uses ethylene oxide to sterilize medical equipment. According to the companies’ own self-reported emissions data in 2017, Vantage released 2,160 pounds of EtO¹ and Medline released 2,863 pounds.²

In the December 2016 Report on the Integrated Risk Information System (“IRIS”) for the Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, EPA found that “confidence in

¹ See Appendix A. Annual Emissions Report APCA0531 (Dec. 20, 2017) for Vantage Specialties Inc. (097035AAQ), Illinois Environmental Protection Agency, Division of Air Pollution Control.

² See Appendix B. Annual Emissions Report APCA0511 (Dec. 28, 2017) for Medline Industries Inc. (097190AFG), Illinois Environmental Protection Agency, Division of Air Pollution Control.

the hazard characterization of EtO as ‘carcinogenic to humans’ is high.”³ The 2016 IRIS report also stated that EtO is mutagenic and can cause tumors in the lymphohematopoietic system, brain, lung, connective tissue, uterus, and mammary gland.

Over 23,000 people live within a one-mile radius of Vantage in Gurnee, and more than 19,000 people live within the same proximity of Medline in Waukegan.⁴ Each of these facilities is located within a mile of at least one school. There are a total of 10 schools, mostly for elementary or middle school children, within 5 miles of the two facilities.⁵

According to the EPA’s Toxic Release Inventory Program’s 2017 data, there are approximately 200 other industrial facilities in the U.S. that release ethylene oxide into the air.⁶ In the proposed amendment, EPA stated the maximum facility-wide cancer maximum individual risk (“MIR”)—“mainly driven by ethylene oxide emissions”—was 600-in-1 million (or 6 in 10 thousand).⁷ That MIR greatly exceeds the presumptive limit on MIR cancer risk of 1 in 10 thousand.

EPA’s own data and findings show that ethylene oxide is a highly carcinogenic and hazardous air pollutant that puts the public health of several communities across the country at risk. These findings were confirmed by a recent study by the Illinois Department of Public Health, which found significantly elevated numbers of actual cancer incidences in both children and adults for Hodgkin’s lymphoma, breast cancer, pediatric lymphoma, prostate cancer, female pancreatic cancer, and ovarian cancer—the types known to be associated with EtO exposure—in the vicinity of the Sterigenics facility in Willowbrook, Illinois.⁸

The EAC strongly urges EPA to continue in its efforts to address ethylene oxide emissions and to begin reducing emissions in accordance with the best available science. In the following paragraphs, the EAC provides specific comments and suggestions to ensure that ethylene oxide regulations will best protect public health and comply with the Clean Air Act.

1. EPA Should Not Seek or Consider Public Comments on Updating the Risk Value of Ethylene Oxide in this Rulemaking.

The proposed rule presents the results of the residual risk and technology reviews (“RTRs”) of the HCl production source category and proposes to amend the NESHAP for the

³ U.S. EPA. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-16/350F, 2016 [hereinafter 2016 IRIS Report], *available at* https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730.

⁴ <https://www.change.org/p/stop-eto-in-lake-county-ban-ethylene-oxide-emission-in-il>

⁵ See Appendix C. Google Maps.

⁶ Found on TRI EZ Search, *available at* https://iaspub.epa.gov/enviro2/ez_column_v2.list?database_type=TRI&table_name=V_TRI_AIR_EZ.

⁷ 84 F.R. 1583.

⁸ “IDPH Releases Cancer Assessment for Area Surrounding Sterigenics Facility,” Illinois Department of Public Health (Mar. 29, 2019), *available at* <http://dph.illinois.gov/news/idph-releases-cancer-assessment-area-surrounding-sterigenics-facility-0>.

HCl production source category. The only two hazardous air pollutants (“HAP”) emitted for the HCl production source category are HCl and Cl₂ (chlorine gas). The inhalation risk assessment for these two HAPs showed that there is no quantifiable cancer risk posed by the source category, since neither HCl nor Cl₂ are known or suspected carcinogens.⁹

However, the facility-wide risk assessment resulted with a facility-wide cancer MIR of 600-in-1 million, due to ethylene oxide emissions from a variety of industrial processes at the same facility—“none of which are part of [the HCl] source category.”¹⁰

This rulemaking, which proposes amendments to the HCl Production source category under Section 112 of the Clean Air Act, is not the proper vehicle to address the risk value of ethylene oxide. EtO is an entirely unrelated HAP that is not emitted by HCl production.

The inhalation unit risk (“IUR”) value for EtO was established through the systematic, peer-reviewed IRIS Program. The IRIS Program sits within EPA’s National Center for Environmental Assessment in the Office of Research and Development (“ORD”). As EPA’s website explains, the “placement of the IRIS Program in ORD is intentional” because it “ensures that IRIS can develop impartial toxicity information independent of its use by EPA’s program and regional offices to set national standards.”¹¹

If EPA wants to modify or update the EtO IUR, or simply wishes to solicit public comment, it must do so under a proposed rulemaking with an explicit title about ethylene oxide and the IRIS IUR with a clear proposal as to what action EPA wants to take. This would give notice to all interested parties and communities that are affected or exposed to ethylene oxide. Like other rulemakings related to IRIS risk values, EPA should also include instructions on how to provide technical comments.

2. The Updated Risk Value of Ethylene Oxide from the 2016 IRIS Report is Based on High-Quality Science and Should Not Be Undermined.

There is no basis for reconsideration of the 2016 IRIS Report. Instead, EPA should reaffirm the high confidence of the IUR estimates based on the high-quality science that was used to establish the risk estimates.

As the IRIS Report detailed, EtO’s hazard characterization as “carcinogenic to humans” was based on “strong epidemiological evidence supplemented by other lines of evidence.”¹² Furthermore, the EtO risk estimate was based on human data from a large, high-quality epidemiology study with individual worker exposure estimates. The National Institute for Occupational Safety and Health (“NIOSH”) scientists who conducted the studies put “extensive effort into addressing [the] issue by developing a state-of-the-art regression model to estimate

⁹ 84 F.R. 1582.

¹⁰ 84 F.R. 1583.

¹¹ Basic Information about the Integrated Risk Information System, U.S. Environmental Protection Agency, available at <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>.

¹² 2016 IRIS Report, *supra*, note 3.

unknown historical exposure levels using variables, such as sterilizer size, for which historical data were available.”¹³ Finally, the use of linear low-exposure extrapolation was strongly supported by the fact that EtO has a mutagenic mode of action.

The IRIS Report concluded that there was a “relatively high confidence in the total cancer unit risk estimate” for both breast cancer and lymphoid cancer. The NIOSH studies used to establish the risk estimates were rigorously peer-reviewed, including by the Science Advisory Board.¹⁴

After EPA revised the draft assessment several times, the assessment was released for external peer review as well as public comments.¹⁵ EPA even hosted an IRIS public science meeting to discuss the draft assessments for ethylene oxide. It was only after this rigorous review and revision process that EPA published the final IRIS Report in December 2016.

Since then, there has not been any new scientific data or study to dispute or contradict the 2016 IRIS conclusions. As such, there is no need to doubt the 2016 IUR or to reevaluate the EtO risk estimates that have already been completed by IRIS.

In fact, a recent study surveying cancer incidences by the Illinois Department of Public Health (“IDPH”) strongly supports the 2016 IRIS findings. In a survey of the areas surrounding Sterigenics—an EtO sterilization facility that was placed under seal order by Illinois EPA in February 2019—IDPH found that:

- Breast cancer was higher in both study areas compared to the five collar counties, about 10% higher (747) than expected (681) in Study Area 1, and 7% higher (1,548) than expected (1,445) than expected in Study Area 2, but not significantly compared to the county;
- A steady, but slight increase in non-Hodgkin’s lymphoma in women became more pronounced beginning in 2009 in both study areas;
- Pediatric lymphoma cases were also elevated among females for both study areas for the duration of the study; and
- Other adult cancers observed to be diagnosed at higher rates than the county include:
 - Prostate
 - Study Area 1 – 680 diagnosed vs. 630 expected
 - Study Area 2 – 1,367 diagnosed vs. 1,287 expected
 - Female pancreatic
 - Study Area 1 – 77 diagnosed vs. 59 expected
 - Study Area 2 – 151 diagnosed vs. 126 expected
 - Ovarian

¹³ 2016 IRIS Report, *supra*, note 3.

¹⁴ Science Advisory Board Review of the EPA’s *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*, EPA-SAB-15-012, U.S. Environmental Protection Agency, *available at* <https://yosemite.epa.gov/sab/sabproduct.nsf/0/BD2B2DB4F84146A585257E9A0070E655/%24File/EPA-SAB-15-012+unsigned.pdf>.

¹⁵ Ethylene oxide background, *available at* https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=329730.

- Study Area 1 – 84 diagnosed vs. 67 expected.

3. **EPA Should Use the Updated Risk Value in Future Regulations and Standards for Ethylene Oxide.**

EPA states that it plans to (1) review Clean Air Act regulations for facilities that emit ethylene oxide and (2) get additional information on ethylene oxide emissions to “evaluate opportunities to reduce ethylene oxide emissions.”¹⁶ EAC and Stop EtO in Lake County fully support EPA’s proposal to reduce EtO emissions and urge EPA to quickly review existing regulations related to EtO and update them to reduce acceptable emissions levels in light of the 2016 IRIS risk estimates.

The 2014 NATA map shows 58 EPA monitoring tracts across 12 states that have EtO air emissions at levels that pose cancer risks at a rate greater than 1 in 10 thousand people, exceeding EPA’s presumptive limit on MIR cancer risk.¹⁷ As the Agency for Toxic Substances and Disease Registry (“ATSDR”) recognized in its 2018 health consultation report, the updated IRIS risk value increased ethylene oxide’s potency for cancer by 30 times, from 0.0001 per microgram per cubic meter ($\mu\text{g}/\text{m}^3$) to 0.003 per $\mu\text{g}/\text{m}^3$.¹⁸ EPA must update existing regulations to reflect the newfound toxicity of EtO and reduce emissions to protect public health for people all over the country.

Some rules related to ethylene oxide that should be amended include the regulations for: Commercial Sterilizers (last updated in 2006),¹⁹ Miscellaneous Organic Chemical Manufacturing (last updated in 2006),²⁰ Hospital Ethylene Oxide Sterilizers (last updated in 2007),²¹ Polyether Polyols Production (last updated in 2014),²² and Synthetic Organic Chemical Manufacturing Industry (last updated in 2006).²³

¹⁶ 84 F.R. 1584.

¹⁷ Dan West, Action Needed to Protect Americans from Toxic EtO Pollution, Natural Resources Defense Council, available at <https://www.nrdc.org/experts/dan-west/action-needed-protect-americans-toxic-eto-pollution>.

¹⁸ Evaluation of Potential Health Impacts from Ethylene Oxide Emissions, U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, August 21, 2018 available at https://www.atsdr.cdc.gov/HAC/pha/sterigenic/Sterigenics_International_Inc-508.pdf.

¹⁹ Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants (NESHAP), U.S. Environmental Protection Agency, available at <https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>.

²⁰ Miscellaneous Organic Chemical Manufacturing: National Emission Standards for Hazardous Air Pollutants (NESHAP), U.S. Environmental Protection Agency, available at <https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission>.

²¹ Hospital Ethylene Oxide Sterilizers: National Emission Standards for Hazardous Air Pollutants (NESHAP), U.S. Environmental Protection Agency, available at <https://www.epa.gov/stationary-sources-air-pollution/hospital-ethylene-oxide-sterilizers-national-emission-standards>.

²² Polyether Polyols Production: National Emission Standards for Hazardous Air Pollutants (NESHAP), U.S. Environmental Protection Agency, available at <https://www.epa.gov/stationary-sources-air-pollution/polyether-polyols-production-national-emission-standards-hazardous>.

²³ Synthetic Organic Chemical Manufacturing Industry: Organic National Emission Standards for Hazardous Air Pollutants (NESHAP) - 40 CFR 63 Subparts F,G,H,I, U.S. Environmental Protection Agency, available at

4. EPA Should Urge States to Review Existing CAA Permits and Monitor Ethylene Oxide Emissions.

While EPA is in the process of updating federal ethylene oxide regulations, it should issue an interim rule to provide guidance to states that issue CAA permits for ethylene oxide emissions. EPA has good cause to issue an interim rule without prior notice or opportunity for public comment because of the urgent need to address ethylene oxide emissions throughout the country.²⁴ An interim rule to establish ethylene oxide's newfound toxicity and risk value would also allow states and other agencies to comment on EPA's interim rule and inform EPA on how to draft its final rules.

Facilities with valid CAA permits may be emitting EtO at levels that far exceed safe concentrations. On February 15, 2019, Illinois EPA issued a seal order to stop the use of ethylene oxide at Sterigenics U.S., LLC in Willowbrook, IL. Illinois EPA found that "elevated cancer risks present[ed] a public health hazard" to residents and off-site workers around Sterigenics.²⁵

Sterigenics' permit allows up to 36,400 pounds of ethylene oxide emissions each year—32,195 more pounds than Sterigenics actually emitted in 2016.²⁶ Releasing less than 12% of the legally permitted emissions was found to present an immediate risk to the health of the surrounding community and Illinois EPA ordered a discontinuation of all EtO use at that facility in order to protect public health.

Other communities, like Gurnee and Waukegan, face similar threats. In Gurnee, Vantage self-reported 2,160 pounds of ethylene oxide emissions in 2017.²⁷ In Waukegan, Medline released 2,862 pounds.²⁸ The fact that all these facilities are operating within their existing CAA permits points to the immediate need for EPA to act urgently.

The EAC also urges EPA to recommend in its interim rule that states begin their own monitoring initiatives to better understand current ethylene oxide emissions and the threat to public health. Collaborative monitoring and additional data from different industries in different geographic settings would hasten EPA's rulemaking process and promote the most efficient process for reducing ethylene oxide emissions.

<https://www.epa.gov/stationary-sources-air-pollution/synthetic-organic-chemical-manufacturing-industry-organic-national>.

²⁴ See Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(B) ("Except when notice or hearing is required by statute, this subsection does not apply . . . when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.").

²⁵ Illinois EPA Director Seals Portions of Sterigenics Due to Public Health Hazards from Ethylene Oxide Emissions, Illinois.gov News, available at <https://www2.illinois.gov/Pages/news-item.aspx?ReleaseID=19717>.

²⁶ TRI Facility Report: Sterigenics US LLC-Willowbrook IL Facility (60521GRFFT7775Q), available at <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Release/60521GRFFT7775Q>.

²⁷ See Appendix A, *supra*, note 1.

²⁸ See Appendix B, *supra*, note 2.

Creating models based on existing data—such as that from the Sterigenics plant in Willowbrook, IL²⁹—is insufficient to properly understand EtO emissions. Collecting more data from different types of facilities that release ethylene oxide will better inform how different pollution control measures, wind patterns, and precipitation affect emissions. The limited data set from Willowbrook has unexplained anomalies and should not be the sole basis to determine risk assessments and new standards.³⁰

Conclusion

EPA is mandated by the Clean Air Act to regulate to protect the health of the people living in the United States. There is no question, based on EPA's own extensive science-based and peer-reviewed studies that ethylene oxide presents a clear danger to public health, with the greatest danger born by children. The 2016 IRIS study is sound and supported by the even more recent study of actual cancer incidences in the vicinity of the Sterigenics facility in Willowbrook, Illinois.

Notably in the IDPH study, young girls suffered a particularly high incidence of pediatric lymphoma. The answer to this urgent public health problem is not for EPA to initiate a process to undermine the science behind the IRIS report. The science is sound and people are being harmed by EPA's inaction. We urge EPA to move forward with due urgency to revise its regulations related to EtO use to reflect this science and to assist states to review existing permits, monitor EtO emissions, and take immediate steps to control these emissions. This hazardous air pollutant threatens communities, plant workers, and children all over the country and must be addressed promptly before any more harm occurs.

Thank you for your consideration of these comments.

Sincerely,



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²⁹ Sterigenics Willowbrook Facility – Latest Update, U.S. Environmental Protection Agency, *available at* <https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update>.

³⁰ Michael Hawthorne, Air testing after Sterigenics was shut down shows 'rapid drop' in cancer-causing gas in Willowbrook, EPA official says, the Chicago Tribune, Mar. 20, 2019 (“[U]nexplained concentrations of ethylene oxide continue to be detected at some locations even though Sterigenics isn't releasing it into the air. Possible sources include other upwind facilities or lingering emissions from Sterigenics, Mike Koerber, associate director for policy at the EPA's Office of Air Quality Planning and Standards, said during the seminar.”).